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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,075	01/23/2004	Thomas Briese	5199-87	7998

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EXAMINER	
MOSHER, MARY	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/764,075	BRIESE ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *11-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 25-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 January 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/7/04, 4/18/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of SEQ ID NO:2 in the reply filed on May 6, 2005 is acknowledged. The traversal is on the ground(s) that each of the species represents an oligonucleotide primer set, all of the sequences derive from corona virus, and are closely related in function, effort, and mode of operation. This is not found persuasive because the claims, as written, are actually drawn to single nucleic acids. E.g., in claim 8, the preamble states a "primer set" but the body of the claim requires only one nucleic acid, which is a >10 nt sequence chosen from the group consisting of the N region, the 3' NCR, the complement of N region, and the complement of 3' NCR. Each of seqs 2-16 is an alternative to the others, each is distinct in structure from the others, each targets a different sequence in the SARS genome, and each requires a separate search.

The requirement is still deemed proper and is therefore made FINAL.

Claims 11-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 6, 2005.

Specification

The disclosure is objected to because of the following informalities: Sequence recitations occur in the specification without the required SEQ ID NO identifiers, see pages 16 and 20. A cursory inspection of the Sequence Listing indicates that some or

all of these sequences are absent from the Listing. Also, Figure 1 includes a number of sequence recitations but neither the figure or its brief description include the required SEQ ID NO identifiers. In addition, cursory inspection indicates that the long sequences recited in Figure 1 are not the same as SEQ ID NO:1, and therefore some or all of the sequences disclosed in Figure 1 are absent from the Listing. Full compliance with the sequence rules requires all sequence disclosures to be included in the Listing, regardless of whether they occur in the text or the figures and regardless of whether they are novel or known in the prior art.

Appropriate correction is required.

Drawings

The drawings are objected to because Figure 4 was filed as a color drawing.

Color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

> The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

Alternatively, the figure could be replaced with an equivalent black-and-white drawing.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

Claims 1-10, 25-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 4, 7, 8, 27, 29, 33 are indefinite in reciting "comprising 10-30 consecutive nucleotides." The open "comprising" conflicts in scope with the closed range "10-30 nucleotides," does the language mean "comprising 10" or does it mean

"10-30" ? In addition, in claims 9, 28, 30, and dependent claims, does the primer consist of or comprise the recited SEQ ID structure?

Claims 3, 6, and 26 are drawn to methods, but are incomplete in that they do not recite any active step. "Utilizing in a kit" does not indicate anything about the process being carried out, except maybe that it occurs in some sort of container. While all of the technical details of a method need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is to be practiced. The minimum requirements for method steps include a contacting step in which the reaction of the sample with the reagents necessary for the assay is recited, a detection step in which the reaction steps are quantified or visualized, and a correlation step describing how the results of the assay allow for the determination. In these claims, all of the steps are missing. Claims 33-34 include a contacting step, but lack a detection step and a correlation step, so they are also incomplete.

Claims 9, 10, 28, 30 are indefinite in reciting "fragment, variant, and derivative thereof." The claims do not place any limitation on the length of a fragment (is a dimer encompassed?), and the terms "variant" and "derivative" open the scope of the claim to any nucleic acid sequence. Since the specification does not teach what "variants" and "derivatives" are capable of performing the intended use of "determining the presence or absence of SARS-associated corona virus," it is unclear what materials are encompassed by the claimed products.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 25, 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Fodor et al US 2001/0053519. Fodor teaches an array which comprises every possible sequence of 10 residues of DNA, see Example 2, page 12. This complete set of 10-mers necessarily and inherently comprises all of the 10-mers of claims 1, 4, and 7, and also comprises any possible set of 10-mers of claim 8. The array also constitutes a composition, as required by claims 2, 5, and 25, and the 10-mers in the array constitute fragments, variants, and derivatives of the sequences of claims 9-10. In regard to method claims 3, 6, and 26, since the only active step is "using in a kit", the reference teaches using the array, and the array itself constitutes a kit. Therefore the reference meets each and every limitation of these claims.

Claims 1, 4, 7-10 are rejected under 35 U.S.C. 102(a) as being anticipated by Genbank locus AY274119. The Genbank entry discloses a synthetic DNA which comprises SEQ ID NO:1 and SEQ ID NO:2, thereby meeting each and every limitation of these claims. See nucleotides 28491-29630. This Genbank entry was publicly available on April 14, 2003. Please note, the website "SARS-associated Coronavirus" is cited as evidence that similar sequence data was publicly available 2 days earlier.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fodor et al. These claims differ from Fodor in requiring instructions for use, and in requiring PCR reagents. Please note, an applicant is not entitled to patent a known product by simply attaching a set of instructions to that product, see In re Ngai, 70 USPQ2d 1862 (CA FC 2004), regardless of the content of the instructions. Since instruction sheets are conventional attachments to commercial products, addition of a sheet of instructions for use of the array is seen as obvious. Furthermore, Fodor suggests using the array in a method involving PCR, see paragraph 0108, and packaging the array in association with PCR reagents for the purpose of convenience is

seen as obvious. The invention as a whole is therefor prima facie obvious, absent unexpected results.

Claims 1-10, 25-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Ksiazek et al (New England Journal of Medicine 348(20):1953-1966, published online April 10, 2003), Genbank Accession AY274119, and either Vabret et al (Journal of Virological Methods 97:59-66, 2001) or Stewart et al (In: Y. Becker and G.Darai, Eds, Diagnosis of Human Viruses by Polymerase Chain Reaction Technology, Springer-Verlag, New York (1995), pp. 316-327). Ksiazek teaches a PCR method for identifying a coronavirus associated with the new and deadly disease, SARS. This differs from the claimed invention in that reference used primers and probes for the polymerase gene, not the N or 3' noncoding region. However, the Genbank accession teaches the sequence of a full SARS viral genome, and Vabret and Stewart both teach successful diagnosis of other human coronaviruses using probes and primers from the N gene region. It would have been within the ordinary skill of the art to design alternative probes and primers from the full SARS genomic sequence. The previous success of N gene probes and primers for detecting other human coronaviruses, as reported by Vabret and other references cited within, provides motivation to choose the N gene region as an alternative to the polymerase gene region used by Ksiazek. Absent unexpected results, therefore, the invention as a whole is seen as prima facie obvious.

Information Disclosure Statement

The documents lined through in the information disclosure statement filed 9/7/2004 have not been considered, because the file does not include a copy of those documents.

The publication by Chin (4/18/2005 IDS) is cited as of interest, as teaching a collection of oligonucleotides similar to Fodor et al but extending to 12 bases in length.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. **On July 15, 2005, the Central FAX Number will change to 571-273-8300.**

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

7/11/05

MARY E. MOSHER, PH.D.
PRIMARY EXAMINER